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Washington, D.C. 20231

MAR 20 1997

Gregg C. Benson
Pfizer, Inc.
Patent Department
Eastern Point Road
Groton, CT 06340

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,525,358

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,525,358, which claims the human drug product ZYRTEC™, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 5 years.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of May 29, 1996 (61 Fed. Reg. 26913). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,103) + 2,717 \\ &= 3,269 \text{ days (8.96 years)}\end{aligned}$$

Since the regulatory review period began May 31, 1984, before the patent issued (June 25, 1985), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From May 31, 1984 to June 25, 1985 is 390 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period: $1,493 - 390 = 1,103$ days.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The five year limitation of 35 U.S.C. § 156(g)(6)(A) applies in the present situation because the patent was issued after the date of enactment (September 24, 1984) of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(A), the period of extension will be for five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such

request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 5 years.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	4,525,358
Granted	:	June 25, 1985
Original Expiration Date	:	June 25, 2002
Applicant	:	Eugène Baltes et al.
Owner of Record	:	UCB Pharmaceuticals, Inc.
Title	:	2-[4-(DIPHENYLMETHYL)-1-PIPERAZINYL]-ACETIC ACIDS AND THEIR AMIDES
Classification	:	514/255
Product Trade Name	:	ZYRTEC™
Term Extended	:	5 years
Expiration Date of Extension	:	June 25, 2007

Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520
2011 Crystal Drive
Arlington, VA

Telephone inquiries related to this determination should be directed to Karin Tyson at (703) 306-3159.



Hiram H. Bernstein
Senior Legal Advisor
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Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
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RE: ZYRTEC™
FDA Docket No.: 96E-0046